JUL 1 7 2000

K001386

510k SUMMARY
ACCUSET SENSOR
Date Prepared: 7/11/00

1. **CONTACT PERSON**
   Walter D. Wallach, President
   Phone: 949 - 365-5701

2. **NAME OF THE MEDICAL DEVICE**
   Proprietary name: AccuSet Sensor

3. **DEVICE CLASSIFICATION**
   The Food and Drug Administration has not classified the AccuSet Sensor under 21 CFR Parts 862 – 892.

4. **STATEMENT OF SUBSTANCIAL EQUIVALENCE**
   The AccuSet Sensor is substantial equivalent to the Vaginal Probe & Perineometer by Biosearch Medical Products (K970145) and the Rectal Balloon Catheter by Rusch International (K952573). Table 1 shows a comparison of the AccuSet Sensor with these devices.

5. **INTENDED USE**
   The AccuSet can be used to monitor the amount of tension between the sling and urethra during pubovaginal surgery and monitor the tension between adjacent soft tissue during surgery.

6. **DESCRIPTION OF DEVICE**
   The AccuSet Sensor consists of a modified balloon catheter that uses a sealed column of air to indicate pressure/tension as the balloon is squeezed between the sling and urethra. A handle allows the surgeon to place the AccuSet Sensor in the desired location. The AccuSet Sensor is a single use device. It is supplied sterile and non-pyrogenic. A diagram of the AccuSet Sensor is shown in Figure 1.

7. SUBSTANCIAL EQUIVALENCE COMPARISON

Table 1. Substantial Equivalence Matrix for the AccuSet Sensor

Attribute	AccuSet Sensor	Vaginal Probe by Biosearch Medical Products (K970145)	Rectal Balloon Catheter by Rusch International (K952573)
Probe/Balloon designed to fit appropriate anatomical location	Yes	Yes	Yes
Product designed to measure/transmit pressure	Yes	Yes	Yes
Fluid used for pressure measurement and transmission	Air	Air	Sterile Water
Probe/balloon material	Biocompatible Polymer	Biocompatible Polymer	Natural Latex Rubber
Probe/Balloon design	Smooth Rounded Tip	Smooth Rounded Tip	Smooth Rounded Tip
Tubing material	Biocompatible Polymer	Biocompatible Polymer	Biocompatible Polymer
Connector to Monitor	Female luer	Female luer	Female luer
Product is single use.	Yes	Patient can reuse after cleaning	Yes
Product supplied sterile	Yes	No	Yes

As Table 1 shows the AccuSet Sensor is technologically identical to the predicate devices in that a column of fluid is used to indicate pressure and transmit it to a monitor. All three devices use similar designed pressure sensing tips (balloon/probe) and are manufactured using biocompatible materials. The major difference among these three devices is the anatomical location where they are used.

8. SUMMARY OF SAFETY TESTING

The AccuSet Sensor is made from known medical grade polymers. The polymer suppliers have conducted extensive biocompatibility tests including USP Class VI for plastics, direct contact hemolysis, cytotoxicity, and 30 day muscle implantation studies. Results of all studies support the biocompatibility of the polymers used in the AccuSet Sensor. In accordance with the Food and Drug Administration "General Purpose Memorandum G95-1 Use of International Standard ISO-10993" for external communicating devices with limited body contact, PelviCare Inc. had the follow tests performed at a contract laboratory:

Acute Systemic Toxicity
Intracutaneous Reactivity
Cytotoxicity
Isosensitization Assay

All tests were conducted on finished sterilized product and support the conclusion that the polymers used in the AccuSet Sensor are biocompatible.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 17 2000

Mr. Michael Oldham
Regulatory Affairs
PelviCare Inc.
28202 Cabot Road, Suite 300
Laguna Niguel, CA 92677

Re: K001386
AccuSet™ Sensor, Model 2000
Dated: May 1, 2000
Received: May 2, 2000
Regulatory Class: II
21 CFR 876.1620/Procode: 78 FEN
21 CFR 884.1425/Procode: 85 HIR

Dear Mr. Oldham:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

510k Number (if known): K001386

Device Name: AccuSet Sensor

Indications For Use:

The AccuSet Sensor can be used to monitor the amount of tension between the sling and urethra during pubovaginal sling surgery and monitor the amount of tension between adjacent soft tissue during surgery.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: ✓ OR Over-the-Counter Use: _____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K001386